

CLAIMS

We claim:

1 1. A method for controlling the rate of release of a biologically active protein
2 comprising the step of adding the protein to a completely biodegradable blend of about 95 to 5%
3 by weight of a homopolymer of ε-caprolactone and about 5 to about 95% by weight of a
4 crystallization modifier selected from the group consisting of crystalline fatty acids and
5 crystalline esters of fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric
6 alcohols.

1 2. The method of claim 1 wherein the crystallization modifier is crystalline
2 esters or fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric alcohols.

1 3. The method of claim 2 wherein the polyhydric alcohols are selected from
2 the group consisting of glycerol, ethylene glycol and propylene glycol.

1 4. The method of claim 3 wherein the polyhydric alcohol is glycerol
2 monostearate.

1 5. The method of claim 1 wherein the protein is selected from the group
2 consisting of enzyme, peptide and antibody.

1 6. The method of claim 1 further comprising lyophilizing a solution
2 containing the protein before adding the protein to the blend.

1 7. The method of claim 1 wherein the protein is added in the amount ranging
2 from about 1% to about 60 % by weight of the blend.

1 8. The method of claim 7 wherein the protein is added in the amount
2 ranging from about 10% to about 40% by weight of the blend.

1 9. A method for controlling the rate of release of a biologically active protein
2 comprising the step of adding the protein to a completely biodegradable blend of about 95 to 5%
3 by weight of a copolymer of at least 80% by weight ϵ -caprolactone and corresponding remainder
4 weight of another absorbable monomer; and about 5 to about 95% by weight of a crystallization
5 modifier selected from the group consisting of crystalline fatty acids and crystalline esters of
6 fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric alcohols.

1 10. A completely biodegradable preparation providing extended release of a
2 biologically active protein comprising an effective amount of the protein in a blend of about 95
3 to 5% by weight of a homopolymer of ϵ -caprolactone and about 5 to about 95% by weight of a
4 crystallization modifier selected from the group consisting of crystalline fatty acids and
5 crystalline esters of fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric
6 alcohols.

1 11. The preparation of claim 10 wherein the protein is an enzyme.

1 12. The preparation of claim 11 wherein the enzyme is alkaline phosphatase.

1 13. The preparation of claim 10 wherein the protein is a peptide.

1 14. The preparation of claim 13 wherein the peptide is leuprolide acetate.

1 15. The preparation of claim 10 wherein the protein is an antibody.

1 16. The preparation of claim 15 wherein the antibody is anti-EM.

1 17. The preparation of claim 10 wherein the crystallization modifier is
2 crystalline esters of fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric
3 alcohols.

1 18. The preparation of claim 17 wherein the polyhydric alcohols are selected
2 from the group consisting of glycerol, ethylene glycol and propylene glycol.

1 19. The preparation of claim 18 wherein the polyhydric alcohol is glycerol
2 monostearate.

1 20. The preparation of claim 10 wherein the homopolymer of ϵ -caprolactone
2 is present in the amount ranging from about 70% to about 30% by weight of the blend and the
3 crystallization modifier is present in the amount ranging from about 30% to about 70% by
4 weight of the blend.

1 21. The preparation of claim 20 wherein the homopolymer of ϵ -caprolactone
2 and the crystallization modifier are each about 50% by weight of the blend.

1 22. A completely biodegradable preparation providing extended release of a
2 biologically active protein comprising an effective amount of the protein in a blend of about 95
3 to 5% by weight of a copolymer of at least 80% by weight of ϵ -caprolactone and corresponding
4 remainder weight of another absorbable monomer; and about 5 to about 95% by weight of a
5 crystallization modifier selected from the group consisting of crystalline fatty acids and
6 crystalline esters of fatty acids which are saturated C₁₂-C₁₈ fatty acid esters of polyhydric
7 alcohols.